

YEAR 6 CLINIC VISIT

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YEAR 6 CLINIC VISIT

1. Overview of measurements

All Health ABC participants who attend the Year 6 clinic visit will have the following measurements unless specifically excluded according to criteria described in each chapter:

- In-clinic interview
- Medication inventory update
- Standing Height
- Weight
- Radial pulse
- Blood pressure
- Abdominal circumference
- Thigh circumference
- Sit and reach flexibility
- Bone density (DXA: whole body)
- Isokinetic strength (Kin-Com)
- Isometric strength (chair)
- Grip strength
- Chair stands
- Standing balance
- Balance walks
- 20-meter walk
- Long distance corridor walk
- Hip pain and joint rotation
- Assessment of arthritis/knee pain
- Phlebotomy
- Computed tomography (CT)

Subgroups of participants may have the following measurements:

- Bone density (DXA: hip – for those who did not have a hip scan during Year 5)
- Knee x-ray (participants with new knee pain or follow-up subgroup)
- Knee MRI (follow-up subgroup)

After the completion of each component of the Health ABC Year 6 clinic visit, the Procedure Checklist should be completed (see Appendix 1). Consent for release of results to physicians should also be indicated on the cover sheet of the Health ABC Year 6 Clinic Visit Workbook (Memphis only).

Scripts in protocols and worksheets

It is very important that examiners read the Health ABC operations manual. Scripts are included in the operations manual in order to standardize the administration of the many tests given to participants in the study. These scripts clearly identify key points that are important to convey to the participant. A number of worksheets also include script. Examiners are encouraged to learn the standardized script that appears in the protocols and/or worksheets, but they are free to modify the script in order for the presentation to sound natural, as long the same information is conveyed to the participants and is presented in the same order as the standardized script. There are exceptions to this rule, however. If a protocol indicates that you should use an exact script do not deviate from the required wording.

2. Working with older participants

Participants in our research studies are NOT patients; they are very valued volunteers who deserve to interact with study staff who are always at their best. The participants are people who are willing, for very little in return, to contribute their time, energy, and honesty about their situations in the hope of making a difference. We need to do everything we can to make their time with us an enjoyable experience.

Research participants are free to refuse to have any test completed and/or to answer any questions that we ask. Because people who volunteer for studies tend to be generous people, refusals rarely happen. When they do occur, it is often because they do not understand what is being asked of them or why it is being requested. Take the time to explain. However, if they still refuse, respect this decision as their absolute right and move to another activity or question.

It is imperative that research participants are always treated with respect. This involves, but is not limited to, providing the necessary information to prepare them for their visit, greeting them warmly as they arrive in clinic, thanking them for their participation before the exams are started, answering any questions that they may have, explaining available test results at the end of the visit, thanking them again for their time and interest at the end of the visit, and not wasting their time by making them wait for long periods unnecessarily.

Dealing successfully with older research participants requires that we be sensitive to their potential needs and concerns. These needs may be related to ambulation difficulties, hearing and sight difficulties, discomforts associated with completing the clinic visit (e.g., fatigue due to their health status combined with a long visit, etc.),

competing personal difficulties (e.g., depression, an ill spouse, etc.), and the experience of being a research participant.

The information we collect as research data may identify a new medical problem that may need to be brought to the attention of a participant's primary care physician for follow-up. We, as study staff, do not provide diagnosis or treatment. However, when participant consent has been obtained, we may need to notify appropriate parties (i.e., physicians, participants themselves, proxies, etc.) of a new abnormal finding. This should be accomplished by the clinic coordinator(s) after discussing the finding with the medical director/investigator.

Occasionally participants are wary of finding out that there is something "wrong" with them that they would rather not know. Tread lightly! Participants have a right to have this information remain unreported to them or to their physicians, family members, etc. Again, often their refusal is due to a lack of understanding and/or information. Take the time to discuss their fears. Contact the clinic coordinator to assist in the discussion as needed. However, participants do have the right to refuse to have information made known to themselves and/or others.

Keep in mind that, for the most part, participants who report feeling "fine" are "fine." Relax and enjoy your time with our Health ABC participants!

For Clinic Coordinators and Investigators:

We have an obligation to communicate with our participants and/or their physicians when appropriate. Participants deserve to receive their test results in a timely fashion. These results should be reviewed by the clinic coordinator / investigators prior to being sent to the participant and/or their physician. There should be no surprises when a participant receives their results in the mail. When possible, the clinic coordinator should discuss any abnormal findings with participants BEFORE the results are sent in the mail. Coordinators need to be sure that test results are complete and accurate; and these results must be sent out as quickly as possible.

3. Preparation for the Year 6 clinic visit

3.1 Participant preparation

Each participant who comes to the Health ABC clinic visit will have been told about the contents of the visit during the phone conversation to schedule the clinic visit. Reminder letters should be mailed approximately 7 to 10 days prior to the visit to emphasize the following:

- date and time of the Year 6 clinic visit
- that participants fast for 12 hours prior to their clinic visit (no eating or drinking, except for water and prescription medications)
- that participants take all of their regular medications, as usual, with the following exception: If they have diabetes they are asked NOT to take their insulin or hypoglycemic medications the morning of their clinic visit, and that they should bring these medications to the clinic and take them after the blood draw.
- that participants drink plenty of water before coming into the clinic
- that participants should wear comfortable clothing (short sleeved) and footwear and not wear jewelry or pantyhose or girdles.
- if participants use glasses, that they bring both their reading glasses and any glasses that are used for longer distances.
- that participants who wear hearing aids should bring or wear them to the clinic.
- that participants bring in medications (prescription AND non-prescription and inhalers, if used) that were taken in the last two weeks only.

Ideally, reminder phone calls should be made the day before the clinic visit. Please see an example of a reminder letter in Appendix 2.

3.2 Year 6 clinic visit preparation

At the time of the Year 6 clinic visit, the following should be available for each participant:

- A Data from Prior Visits Report should be generated with information that will be needed for the Year 6 clinic visit (see Appendix 3)

- Your HABC Participant Contact Information report from the Access system with the participant's contact information (address, phone number, proxy, next of kin, power of attorney, etc.).
- A Year 6 Questionnaire labeled with the participant's name, acrostic, and Health ABC enrollment ID number
- A Year 6 Clinic Visit Workbook labeled with the participant's name, acrostic, and Health ABC enrollment ID number
- CT Tracking form
- A Year 6 Participant Results Report to give the participant at the end of their clinic visit (Appendix 4)
- The participant's chart. Field centers should also keep "progress notes" in the participant's chart. Progress notes may be used to record examiner comments and questions, and to document protocol problems and their resolution. Each entry should be dated and signed by the examiner recording the note.

The following should be available for sub-sets of Health ABC participants:

- Bone mineral density results report for those participants who have a hip scan (Appendix 4)
- Knee X-ray Tracking form for participants who are eligible for knee x-rays because they are included in the knee x-ray follow-up subgroup (see Data from Prior Visits Report) or they have new knee pain and have not yet had a knee x-ray.
- Knee MRI Tracking form for participants who are eligible for knee MRIs because they are included in the knee MRI follow-up subgroup. These participants are identified on the Data from Prior Visits Report.

Table 1 [below] lists all the forms that are completed during the Year 6 Clinic Visit; note that the Knee X-ray Tracking form is completed only for participants who are eligible for a knee x-ray, and the Knee MRI Tracking form is completed only for participants who are eligible for knee MRI.

Table 1
Health ABC Year 6 Clinic Visit Forms

Year 6 Questionnaire	Year 6 Clinic Visit Workbook (cont.)
Year 6 Clinic Visit Workbook:	Chair stand
Year 6 Clinic Visit Procedure Checklist	Standing balance
Medication inventory update	Balance walks 20-meter walk
Standing height	Long distance corridor walk
Weight	Hip pain and joint rotation
Radial pulse	Assessment of arthritis/knee pain
Blood Pressure	Knee-xray/MRI eligibility assessment
Abdominal circumference	Phlebotomy
Thigh circumference	Laboratory processing
Sit and reach flexibility	
Bone density (DXA) scan	CT Tracking
Isometric strength (chair)	
Isokinetic strength (Kin-Com)	Knee X-ray Tracking Form
Grip strength	Knee MRI Tracking Form

4. Clinic flow and measurements

4.1 Overview of clinic flow

Every effort should be made to keep the visit as short as possible. One way to save time is to have the participant put on their gown after their blood pressure exams so that they don't have to put on the gown and then take it off. Another time-saving idea is to do tests consecutively that require that participants not be wearing shoes (DXA, height, weight, sit and reach). Also, if the Consent Form is sent out ahead of time, many participants will be ready to sign it right away when they arrive at the field center, instead of taking the time to read it during their clinic visit. The following guidelines for the order of specific measurements are divided into mandatory, which must be followed, and preferable, which are highly recommended but may be modified without jeopardizing the standardization of the measurements:

Mandatory

Blood pressure before Isokinetic Strength (Kin-Com)

Blood pressure and radial pulse before Long distance corridor walk

Year 6 Clinic Visit Workbook Assessment of Knee Pain

(Questions 2, 3, 4, and 5 on pages 41, 42, and 43)

before Knee X-ray Eligibility (page 45 in Year 6 Clinic Visit Workbook)

Preferable:

Blood draw before exams

Group together standing height, weight, abdominal and thigh circumference, bone density scan, and sit and reach flexibility

4.1.1 Year 6 in-clinic follow-up interview

The Year 6 Questionnaire will be administered during the Year 6 clinic visit. The questionnaire does not have to be completed all at once, and can be administered in sections during the course of the clinic visit, with special care that each section be completed.

4.1.2 Medication inventory

Prescription and non-prescription medications used by participants in the two weeks prior to their Year 6 clinic visit will be recorded on the Medication Inventory Form (MIF) in the Year 6 Clinic Visit Workbook. Review the listing on the Data from Prior Visits Report for start dates and dosages of medications that the participant was taking at their last visit. Determine if the participant is still taking the medications listed on the Data from Prior Visits Report. If these medications were taken in the past two weeks, they have to be re-written on the Year 6 Medication Inventory form, but time will be saved if you review the medications that are listed on this form. Also, add any new medications that the participant has used in the past two weeks.

See Chapter 2B for detailed procedures.

4.1.3 Anthropometry and physical measures

A number of anthropometric and physical measurements will be made on all participants who attend the Year 6 clinic visit: standing height, weight, thigh, and abdominal circumference. One of the most important measurements that is done for Health ABC is the weight measurement. The measurement of weight comes early in the exam and offers a good opportunity to answer questions and promote goodwill towards the study.

See Chapters 2E, 2F, and 2K for detailed procedures.

4.1.4 Blood pressure and radial pulse

Sitting and standing blood pressure measurements will be obtained. The sitting blood pressure will be used for the isokinetic strength (Kin-Com) and the standing blood pressure will be used for the 2-minute and long distance corridor walk; individuals with extremely high blood pressure will be excluded from isokinetic strength, the 2-minute walk, and the long distance corridor walk and referred for medical care according to the protocol for referrals. Radial pulse will be taken and individuals with bradycardia or tachycardia will be excluded from the 2-minute walk and the long distance corridor walk.

See Chapter 2G for detailed procedures.

4.1.5 Bone density (DXA)

Bone mineral density of the whole body will be performed using the Hologic QDR 4500 instrument. Body composition measurements are obtained during the whole body scan. Participants who did not have a hip scan during Year 5 should have the BMD of their hip obtained during Year 6 on the same side that was scanned at baseline, unless the participant has had a hip replacement on that side.

See Chapter 2I for detailed procedures.

4.1.6 Sit and reach flexibility

A sit and reach box will be used to measure sit and reach flexibility. It is suspected that flexibility is related to gait characteristics such as stride length, and thus may determine walking speed, an important intermediate end-point of the study.

See Chapter 2R for detailed procedures.

4.1.7 Assessment of arthritis and joint examination

During the Year 6 clinic visit participants will be asked questions regarding knee and hip pain (see pages 39 through 44 in the Year 6 Clinic Visit Workbook). Also, there will be a hip internal rotation examination.

See Chapter 2J for detailed procedures.

4.1.8 20-meter walk

This is a modification of the short walk test used in many epidemiological and clinical studies. The test is divided into two parts.

- the time to walk 20 meters at the participant's usual pace along with the number of steps, and
- the time to walk 20 meters as fast as the participant can, along with the number of steps

See Chapter 2P for detailed procedures.

4.1.9 Isokinetic strength (Kin-Com)

A Kin-Com isokinetic dynamometer will be used to evaluate the concentric strength of the knee extensors.

See Chapter 2L for detailed procedures.

4.1.10 Isometric strength (chair)

The isometric chair is a portable device designed to measure strength with knee extension.

See Chapter 2M for detailed procedures.

4.1.11 Grip strength

Grip strength is a commonly used measure of upper body skeletal muscle function and has been widely used as a general indicator of frailty. Grip strength in both hands will be measured using an adjustable, hydraulic grip strength dynamometer.

See Chapter 2N for detailed procedures.

4.1.12 Performance-based measures (chair stands, standing balance, balance walks)

Direct assessments of physical performance have become standard measurements in epidemiological studies in the elderly. These assessments generally tap multiple domains of physiological performance, including lower extremity strength, balance, coordination, and flexibility. The assessment techniques used in Health ABC have been derived from several previous studies, are reliable when performed in a standardized fashion, and are well tolerated by elderly participants. The following assessments are included in the Health ABC performance battery: single and multiple chair stands, standing balance, and short walk tests with narrowed base of support.

See Chapter 2O for detailed procedures.

4.1.13 Long-distance corridor walk

The Health ABC long distance corridor walk (LDCW) is a two-stage walking-based test of exercise tolerance and fitness level. The first stage consists of a 2-minute walk where participants are instructed to cover as much ground as they can at a pace they can maintain. The second stage consists of the 400-meter walk, which follows after a 30 second pause to get the pulse rate.

See Chapter 2Q for detailed procedures.

4.1.14 Blood collection and processing

The Health ABC Year 6 clinic visit involves the collection of approximately 30 mL of blood: two tubes w/anticoagulant for analysis of HbA₁C and for archiving plasma; and two tubes without anticoagulant so that the blood clots to form serum for analysis of fasting glucose and lipids, and for archiving.

See Chapters 2C and 2D for detailed procedures.

4.1.15 Computed tomography (CT)

The purpose of the CT scan is to provide a means of quantifying the muscle and fat volumes in Health ABC participants. Abdominal and thigh scans are done in Pittsburgh and Memphis. Spine scans are just done in Pittsburgh. The information in the header of the CT Tracking Form (except for Tech ID#) should be completed before the participant is transported to the CT facility; and the form should accompany the participant to the facility. The CT Tracking form is filled out to record whether or not abdominal, thigh, and spine scans were obtained, and if they were not, to record the reason(s).

See Chapter 2H for detailed procedures.

4.2 Substudies

4.2.1 Knee osteoarthritis (OA) assessment – knee x-rays and MRIs

To determine knee x-ray and/or MRI eligibility, follow the instructions on the Knee X-ray and MRI Eligibility Assessment form (page 45 in the Year 6 Clinic Visit Workbook). For those participants who will be having a knee x-ray and/or knee MRI, the information in the header of the Knee X-ray Tracking form and the Knee MRI Tracking form should be completed before the participant goes to the X-ray or MRI facility. The form should accompany the participant to the facility. The accuracy of participant identifiers on forms and images is extremely important.

Repeat knee x-rays

The Year 6 Repeat Knee X-ray Parameter form (attached to the Data from Prior Visits Report) that lists the participant's Health ABC enrollment ID number, name, and acrostic and that includes information regarding previous knee x-ray beam angles and mAs settings should accompany the Knee X-ray Tracking form of those participants who will be having a follow-up knee x-ray.

See Chapter 2S for detailed procedures.

Repeat knee MRIs:

In addition to filling out the header on the Knee MRI Tracking form, the examiner should refer to the Data from Prior Visits Report to see which knee(s) should be scanned, and check the appropriate box(es) on Question #13 (page 3) of the Knee MRI Tracking Form: “Scan Right knee,” and/or “Scan Left knee.” The technician should refer to Question #13 to determine which knee(s) to image.

See Chapter 2T for detailed procedures.

4.3 Procedure checklist and exit interview

At the end of the Year 6 Clinic Visit, an exit interview should be performed to:

- Thank the participant. Be sure the participant knows how much we appreciate their participation.
- Answer questions. Some participants may have questions about various examinations.
- Make sure the Year 6 Clinic Visit Workbook Procedure Checklist is completed; ie., the header information including the Health ABC Enrollment ID #; time of arrival; time of departure; whether the visit included scheduling a knee x-ray or knee MRI; and permission to send test results to the physician (see Appendix 1). Confirm that all exams and measurements were completed. Review the Year 6 Clinic Visit Workbook and complete the Procedure Checklist appropriately. Record on the checklist whether or not a test was completed, was partially completed, whether or not the participant refused a test, or whether the test was not done for some other reason.
- Provide selected results (Appendix 4). Participants will be given the following results:
 - ⇒ Height. Standing height in feet and inches should be provided.
 - ⇒ Weight. Weight in pounds should be provided.
 - ⇒ Blood pressure. Each participant will be given current guidelines for follow-up and evaluation based on the blood pressure recorded.
 - ⇒ Body Composition. The participant will receive a body composition results report that includes their percent body fat and where their results fit in the range of Health ABC participant results.
 - ⇒ Bone mineral density (BMD). Those participants who did not have their hip scanned in Year 5 will have their hip scanned in Year 6. Their BMD will be plotted by the DXA technician on a sex and race-specific normative curve.

- ⇒ Laboratory tests. Cholesterol and blood sugar results will be sent to the participants several weeks after their clinic visit.
- ⇒ Computed Tomography (CT). Results will be sent to participant who have abnormalities.
- ⇒ Knee x-rays and MRIs. Important abnormalities will be reported to participants.
- Summarize future contact with the study both for scheduled visits and endpoints. Participants should be reminded to immediately contact the clinic for any of the following events:
 - ⇒ Hospitalization. Any overnight stay in an acute care facility.
 - ⇒ Surgery. Any surgery requiring regional (e.g., spinal) or generalized anesthesia. This includes same-day surgery that does not result in an overnight hospitalization.
 - ⇒ Fracture. Any broken bone, including minor fractures of the toes, fingers, etc.

Suggested script: “It is very important to the study for us to know as soon as possible about changes in your health. Between study visits, we ask that you call the clinic at this number (xxx) xxx-xxxx, if you are hospitalized overnight, have surgery, or break any bones.”

4.4 Incomplete visits

Occasionally, a participant may not complete their entire clinic visit. They may agree to come in at a later date to have the exams that they missed during their first visit. It is important to minimize the amount of time between the first and the second visit. It is not necessary to reweigh the participants who come in for a second clinic visit. For the DXA exam use the weight that is recorded on page 7 of the Year 6 Clinic Visit Workbook.

Very rarely, a measurement is not taken. Whenever a measurement is not taken, write the reason in the Comments section of the Year 6 Clinic Visit Procedure Checklist, and include a note in the progress notes in the participant's chart explaining why the measurement was not taken.

5. Alerts and notifications

At the clinic visit, participants will receive a report that includes height, weight, blood pressure, and DXA results (see Appendix 4). Table 2 lists measures that have alert values; Appendices 7, 8, and 9 contain examples of alert letters to physicians.

Table 2	
<u>Health ABC Tests: Alert Values</u>	
<u>Defined Values</u>	<u>Examiner Discretion</u>
Blood Pressure	Weight loss $\geq 10\%$
Bone Density	Symptoms during
Fasting glucose	long distance corridor walk

5.1.1 Blood pressure

Immediate alert: ≥ 210 SBP or ≥ 120 DBP, refer to source of care immediately after discussion with the clinic physician.

Below are ranges of blood pressure measurements that require various schedules for referral to sources of care and ranges that are considered to be normal.

180-209 SBP or 110-119 DBP, refer to source of care within 1 week
160-179 SBP or 100-109 DBP, refer to source of care within 1 month
140-159 SBP or 90-99 DBP, confirm within two months
130-139 SBP or 85-89 DBP, high normal, no referral required
<130 SBP or < 85 DBP, normal, no referral required

Blood pressure measurements will be given to the participant at the time of the clinic visit. A printed form with the above referral information and levels, with blanks for recording the participant's values will be provided (see Appendix 4).

5.1.2 Bone density (DXA)

The alert for DXA is loss of bone at a greater rate than 3% a year since baseline. (See Appendix 6 for alert letter to participant and Appendix 7 for the alert letter to physician to be sent after confirmation of excess bone loss from the DXA Reading Center [see Appendix 5 - Excessive Bone Loss Form].)

5.1.3 Long distance corridor walk

If the participant develops chest pain or other symptoms, the clinic supervisor should be notified immediately.

5.1.4 Weight change

Participants with weight loss of $\geq 10\%$ that appears to be unexplained will have the weight change brought to the attention of their physician with the participant's permission (see Appendix 8).

5.1.5 Fasting glucose

Analyte	Reference Range for Reports		Immediate Alerts*
Glucose Metabolism:			
Fasting Glucose	<110 and ≥ 50 mg/dL	Normal	>350 mg/dL OR <50 mg/dL
	110-125 mg/dL	Borderline	
	≥ 126 mg/dL	Elevated**	

See Appendix 9 for physician alert letter.

6. Clinic safety

6.1 Background and rationale

All life threatening emergencies that occur at the Health ABC clinic, such as acute myocardial infarction, should be referred for immediate evaluation at an acute care facility, with emergency measures taken in the clinic before departure. Minor emergencies, such as hypotension or fainting, receive treatment in the clinic. Although most emergencies are of even less severe nature, Health ABC Field Center Clinics are prepared for both types.

6.2 Major emergencies

When a serious life-threatening event occurs in the clinic setting, the primary concern of the clinic staff is to implement pre-established procedures to get the participant to the nearest medical facility. It is imperative that local emergency measures be activated; in most cases, this requires calling 911. Do not take the participant to the emergency room. Let the paramedics do that. At every clinic session a physician, physician assistant, or registered nurse with certification in basic life support is on duty and physically present. Needed life support procedures should be continued until emergency care arrives or the participant is transported to a hospital.

Each Health ABC clinic has specific emergency procedures which define:

1. Who is in charge during the emergency
2. Who administers treatments
3. Who is notified
4. What action clinic staff takes
5. Which reports are filed

Each clinic has, in addition to trained personnel and emergency equipment, posted in a conspicuous place, such as the reception area, the following:

- phone number of police station
- phone number of fire stations
- phone number of ambulance services

} **CALL 911 !**

In each participant's folder, the name and phone number of their physician or usual source of health care is available on a standard Health ABC form. The home and work telephone number of the next-of-kin are also listed.

All medical emergency situations should be coordinated by a physician when present in the clinic. In the physical absence of the latter, this role should be assumed by the charge nurse or senior physician assistant. When not physically present in clinic, they are within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the head nurse and/or senior physician assistant so that the name of the responsible physician is readily accessible. However, in no case should emergency referral and/or care be deferred while staff is attempting to locate a clinic doctor. All personnel should be trained to carry out their specific responsibility during an emergency. Retraining is conducted at least yearly, inclusive of any emergency drill.

All major emergencies should be documented, identifying the type of emergency and action taken. This report should be completed by the clinic coordinator and co-signed by a clinic physician and the Principal Investigator. These reports should be maintained in a central file at each field center and a copy of the report should be kept in the participant's chart.

6.3 Minor emergencies

The most common minor emergency is simple syncope (fainting) and near syncope.

In any situation in which syncope is likely, staff should verify that the participant does not look or feel faint. When the participant looks faint or feels faint the following steps should be implemented:

1. Have the person remain in the chair and sit with their head between their knees or lie down.
2. Crush an ampule of smelling salts and wave under the participant's nose for a few seconds. DO NOT place ampule directly under the nose.
3. Provide the participant with a basin and a towel when they feel nauseous.
4. Check blood pressure and pulse.
5. Have the participant stay in the chair until they feel better and their color returns. Re-check blood pressure and pulse.

If the participant continues to feel sick, recline the chair, place a cold, wet towel on the back of the person's neck, and notify the clinic nurse coordinator. When a participant faints, they should be cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house physician or nurse to assist the participant. The remaining attendant raises the participant's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the participant is breathing. When life support measures are needed, the measures outlined in the above sections are followed.

6.4 Emergency equipment


A basic first aid kit is maintained at each field center. The kit contains a reference guide of its contents, and is checked every 6 months and immediately after each use. At each Field Center, the study coordinator identifies the person responsible for this task.

6.5 Emergency plans in case of fire

1. Notify the emergency management system (911) to report the fire.

2. Close all windows and doors.
3. Escort all participants to the nearest fire exit and assemble a safe distance from the building.
4. Alert the clinic coordinator and the building supervisor of the emergency situation.

APPENDIX 1 Year 6 Clinic Visit Workbook Procedure Checklist

	HABC Enrollment ID #	Acrostic	Date Visit Completed		Staff ID #
	H <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
			Month	Day	Year

YEAR 6 CLINIC VISIT WORKBOOK

Arrival Time:	<input type="text"/> : <input type="text"/>	Departure Time:	<input type="text"/> : <input type="text"/>
	Hours Minutes		Hours Minutes

YEAR 6 CLINIC VISIT PROCEDURE CHECKLIST

Measurement	Page #	Yes: Measurement fully completed	Yes: Measurement partially completed	No: Participant refused	No: Other reason/ Not applicable	Comments
1. Was the Year 6 questionnaire administered?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2. Medication inventory	2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3. Standing height	7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
4. Weight	7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
5. Radial pulse	8	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6. Blood pressure	9	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
7. Abdominal circumference	10	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8. Thigh circumference	11	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
9. Sit and reach flexibility	12	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
10. Bone density (DXA) scan	14	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
11. Isokinetic strength (Kin-Com)	17	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
12. Isometric strength (chair)	21	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
13. Grip strength	24	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
14. Chair stands	26	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
15. Standing balance	27	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
16. Balance walks	29	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
17. 20-meter walk	30	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
18. Long distance corridor walk	31	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
19. Hip pain and joint rotation	39	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
20. Assessment of arthritis/knee pain	41	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
21. Knee X-ray eligibility assessment	45	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
22. Phlebotomy	46	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
23. Laboratory processing	49	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
24. Did participant agree to schedule a CT?		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	
25. Did participant agree to schedule a knee x-ray?		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	
26. Did participant agree to schedule a knee MRI?		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	

Memphis Only:

Would you like us to send a copy of your test results to your doctor? ☐ Yes ☐ NoPage Link #

♦Page 1♦



APPENDIX 2 Year 6 Pre-Visit Instructions

Dear _____:

Your appointment for your Health ABC Year 6 Clinic Visit has been scheduled for: _____, _____ at _____ a.m. at XXXXXXXXXX, XXXXXXXXXX (a map is enclosed). Parking is available in the garage attached to our clinic or van transportation will be provided as prearranged.

Please be sure to review these instructions for your upcoming clinic visit, since they are very important for the success of your tests:

- Read all enclosed materials.
- Please fast for 12 hours prior to your clinic visit (no eating or drinking, except for water and prescription medications).
- Take all your regular medications, as usual, with the following exception:

If you have diabetes, do NOT take your insulin or hypoglycemic medications the morning of your clinic visit. You will take these medications at the clinic after the blood draw. Please be sure to bring these with you.

- Drink plenty of water before you come into the clinic.
- Wear comfortable shoes for walking. It would be helpful if you wear a short sleeved shirt, since this will make taking your blood pressure easier. Do not wear pantyhose or girdles. You will be asked to change clothes for some tests.
- Do not wear jewelry to the clinic, if possible, since this may make it more difficult to do your bone scan.
- If you have glasses, bring both your reading glasses and any glasses that you use for longer distances.
- If you have a hearing aid, bring it with you.
- A plastic bag has been provided for the prescription AND non-prescription medications that you have taken in the last two weeks only. Include eye drops, shots, supplements, vitamins, pain medications, laxatives or bowel medicines, cold medications, cough medications, antacids or stomach medicines, and ointments or salves. Bring these with you to the clinic.

Thank you again for your very valuable help in this important research study! We look forward to seeing you again.

Please call XXX-XXXX if you have any questions about your visit.

APPENDIX 3 Data from Prior Visits Report

Participant Name:

Health ABC Enrollment ID# :

Acrostic:

1. Date of last regularly scheduled contact:
2. Missed Year 5 clinic visit?
- 2a. Reason for missed Year 5 clinic visit:
3. Type of Year 5 contact
4. Has the participant ever had a proxy interview?
- 4a. For which contact?

STANDING HEIGHT

Was the participant standing sideways at the baseline (Year 1) visit when their height was measured?

WEIGHT CHANGE ALERT

1. Participant's weight at their Year 5 clinic visit:
2. Participant's weight at their Year 5 clinic visit minus 10%:

BLOOD PRESSURE

Which arm was used for the baseline (Year 1) blood pressure?

THIGH CIRCUMFERENCE

1. Which thigh was measured at baseline (Year 1)?
2. Midpoint between the inguinal crease and proximal border of the patella: **cm**

BONE DENSITY (DXA) SCAN

1. Did the participant have a hip scan during Year 5?
2. Which hip was scanned at baseline (Year 1)?

ISOKINETIC QUADRICEPS STRENGTH (KIN COM)

1. Which leg was tested at the Year 4 clinic visit?
2. Which leg was tested at the baseline (Year 1) clinic visit?
3. Which hip was scanned at the baseline (Year 1) clinic visit?
4. Manual position for most recent quadriceps strength measurement:
 - a. Dynamometer tilt
 - b. Dynamometer rotation
 - c. Lever arm green C stop
 - d. Lever arm red D stop
 - e. Seat rotation
 - f. Seat back angle
 - g. Seat bottom depth
 - h. Seat bottom angle
 - i. Lever arm length

ISOMETRIC STRENGTH (CHAIR)

1. Has participant ever had an isometric chair measurement?
2. Which leg was tested during the most recent isometric chair measurement?
3. Has participant ever had a Kin-Com exam?
4. Which leg was tested during the most recent isokinetic quadriceps strength Kin-Com exam (not the Year 6 Kin-Com exam)?

Parameters for most recent isometric chair measurement:

5. Seat Height: **mm**
6. Seat Depth: **mm**
7. Lower leg length: **meters**
8. Size of connecting rod:

ECG ALERT

Were there abnormal Marquette ECG hardcopy references collected during the most recent ECG exam?

☐ Yes ☐ No
↓

What abnormalities?

- ☐ Heart rate <40 (bradycardia) or >135 (tachycardia)
- ☐ Wolff-Parkinson-White (WPW) or ventricular pre-excitation
- ☐ Idioventricular rhythm
- ☐ Ventricular tachycardia
- ☐ Third degree or complete A-V block
- ☐ Any statement including reference to acute injury or ischemia, or marked T-wave abnormality

KNEE X-RAY ELIGIBILITY

1. Is the participant eligible for a follow-up knee x-ray?
2. Did the participant have knee symptoms that met eligibility criteria for knee X-ray in Year 2, Year 3, Year 4, or Year 5?
3. Did the participant have a knee x-ray in Year 2, Year 3, Year 4, or Year 5?

KNEE MRI ELIGIBILITY

1. Is the participant eligible for a follow-up knee MRI?
 - 1a. If Yes, which knee should be imaged?

CT TRACKING

Which thigh was measured at baseline?

YEAR 6 REPEAT KNEE X-RAY PARAMETERS

(Attach this form to the front of the Knee X-ray Tracking Form before sending the participant for the knee X-ray.)

Participant Name:
Health ABC Enrollment ID# :
Acrostic:

X-ray Technician Please Note: Use the first beam angle specified below. If a second angle is specified, obtain a second PA film using that angle:

First beam angle: **degrees**

Second beam angle: **degrees**

The following parameters were used on the first knee x-rays for this participant. These should serve as guidelines for setting up the current follow-up knee x-rays. However, if these parameters do not result in a high quality x-rays, then other parameters should be tried to maximize x-ray quality.

mAs setting for the axial view of the right knee: **mA**

mAs setting for the axial view of the left knee: **mA**

MEDICATION INVENTORY

The following is a listing of prescription and non-prescription medications used by the participant in Year 5. Please confirm with the participant whether this information is still current and complete and update the MIF, being careful to determine whether medications listed below were used continuously or whether there is a new start date.

Medication Name	# Used	per D/W/ M	PR N?	Reason for Use	Mo Yr Started	Formul Code	Rx/ Non-Rx
-----------------	--------	------------------	----------	-------------------	------------------	----------------	---------------

EVENTS REPORTED

The following Event Forms have been entered to date for this participant:

Event Form Reference #	Type of Event	Date of Event
------------------------	---------------	---------------

APPENDIX 4 Health ABC Examination Results



Year 6 Participant Results

Participant Name:

(Please Print)

Date of Year 6 Clinic Visit: ____ / ____ / ____
Month Day Year

Height: ____ feet ____ inches

Weight: ____ ____ pounds

Blood Pressure: ____ ____ / ____ ____ mm Hg

Normal:	Less than 130/85 mm Hg
High normal:	130-139 / 85-89 mm Hg
Hypertension:	140/90 mm Hg or higher

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- ☐ Recheck blood pressure within 1 year Comments: _____
- ☐ Recheck blood pressure within 2 months _____
- ☐ See your doctor in 1 month _____
- ☐ See your doctor in 1 week _____
- ☐ See your doctor immediately _____

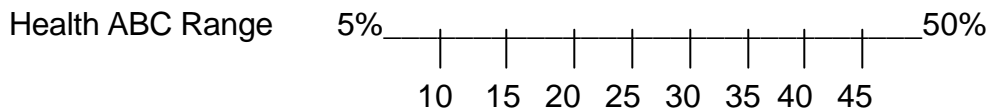
If you have any specific questions about your blood pressure, please talk with your doctor.

BODY COMPOSITION IN MEN

One of the goals of Health ABC is to determine how weight and body composition (fat and lean muscle mass) affect health as we get older. With age, our weight changes and this is often the result of an increase in body fat along with a decrease in lean mass. These changes in body fat and lean mass may lead to an increased risk for health problems and disability. For example, obesity (high percent body fat) may reduce life expectancy by increasing the risk of developing coronary artery disease, high blood pressure, Type II diabetes, certain types of cancer, and several other diseases including arthritis. Although less common, a person may have too little body fat. Since we need a certain amount of body fat (called essential fat) to maintain normal body functions, older men and women with too little fat may also be at risk for health problems.

The bone density test you had during your most recent Health ABC visit also allowed us to measure your percentage of body fat. It is important to measure percent fat in addition to weight alone since *it is the composition of the weight that may be important and not weight alone*. Your percent body fat is written below along with the range in the Health ABC population. There is no exact level of percent body fat that is definitely associated with risk of health problems or disability among all older individuals. As a participant in Health ABC, you are helping us determine what percentage of body fat either maintains or improves health or increases the risk for poor health or disability as we age.

Your Percent Body Fat: _____ %

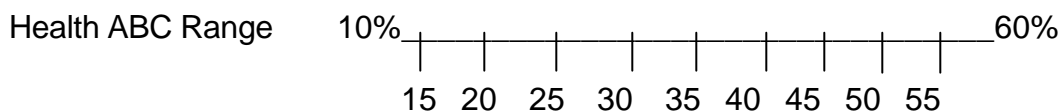


BODY COMPOSITION IN WOMEN

One of the goals of Health ABC is to determine how weight and body composition (fat and lean muscle mass) affect health as we get older. With age, our weight changes and this is often the result of an increase in body fat along with a decrease in lean mass. These changes in body fat and lean mass may lead to an increased risk for health problems and disability. For example, obesity (high percent body fat) may reduce life expectancy by increasing the risk of developing coronary artery disease, high blood pressure, Type II diabetes, certain types of cancer, and several other diseases including arthritis. Although less common, a person may have too little body fat. Since we need a certain amount of body fat (called essential fat) to maintain normal body functions, older men and women with too little fat may also be at risk for health problems.

The bone density test you had during your most recent Health ABC visit also allowed us to measure your percentage of body fat. It is important to measure percent fat in addition to weight alone since *it is the composition of the weight that may be important and not weight alone*. Your percent body fat is written below along with the range in the Health ABC population. There is no exact level of percent body fat that is definitely associated with risk of health problems or disability among all older individuals. As a participant in Health ABC, you are helping us determine what percentage of body fat either maintains or improves health or increases the risk for poor health or disability as we age.

Your Percent Body Fat: _____ %



Laboratory (blood) tests

You will receive the results of your blood tests in several weeks. These results will include your cholesterol and blood sugar.

Computed Tomography (CT) Scans

Computed tomography (CT) is used to measure muscle and body fat. The CT scans are being reviewed and analyzed using special research techniques. You will be notified if abnormalities are found.

Knee X-ray and MRI

Some Health ABC participants had knee x-ray and MRIs. These x-rays and MRIs are being reviewed using special research techniques. These techniques take longer to complete than a standard clinical reading that is done by doctors, so results will not be available for a while. When results are available, you will be notified about important abnormalities.

Muscle strength, flexibility, balance, and walking speed tests

We do not know yet what results are considered “normal” for these tests. You are helping us understand how body changes may cause new health problems and how to prevent disability as we get older. In future years, with your continued participation, we may be able to tell you how your test results compare with others.

We would like to thank you for your continued participation in the Health ABC study. These tests were done for research purposes only and were not intended to diagnose any health problems. However, we encourage you to share these results with your doctor. If you have any questions, please call the Health ABC clinic at:

() _____.

BONE MINERAL DENSITY

Thank you for your continued participation in the Health ABC study. Attached are the results from your bone density test from your Year 6 clinic visit. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this letter is to help you and your doctor understand your bone density measurement.

What is a bone density measurement?

A bone density test measures how much calcium is contained in certain bones, such as the hip. In general, lower bone density and lower calcium means that the bone is weaker.

What do bone density measurements mean?

We all lose bone as we get older, but some people lose bone faster than others. Certain factors can reduce bone density, such as smoking, low calcium intake, lack of exercise, high alcohol intake, use of some medications, and some medical conditions.

Individuals with low bone density have weaker bones, and weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all women and men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

Your hip bone density value was compared to that of young women or men and is at the level checked below:

_____ Normal

_____ Low

_____ Osteoporosis

If your bone density is checked as "low" or "osteoporosis," we suggest that you discuss these results with your personal doctor. We would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a local doctor who specializes in treating osteoporosis.

If you have questions regarding these results, please contact _____
_____ at xxx/xxx-xxxx.



HABC Enrollment ID #					Date of reading:		
H						/	
						/	
					Month	Day	Year

KNEE RADIOGRAPH PARTICIPANT REPORT

Participant name: _____

This report describes what the HEALTH ABC arthritis specialist (rheumatologist) found when they looked at your knee x-rays. If you have any questions about this report, please contact your doctor. This exam was conducted for research purposes only, and was not performed to diagnose any medical conditions.

The examiners were looking for the following:

1. **Osteoarthritis** develops when the cartilage in the joints starts to wear away. This is usually accompanied by changes in the bone near the joint which can be seen on an x-ray. It is the most common form of arthritis.
2. **Osteophytes** are bony growths which form around a joint affected by osteoarthritis.
3. **Joint space** narrowing is a decrease in the space between the joints which occurs when the cartilage wears away.
4. **Cysts** are fluid-filled sacs in the bone near joints affected by osteoarthritis.

① OSTEOARTHRITIS

A. Tibiofemoral joint

LEFT KNEE

RIGHT KNEE

Normal	<input type="checkbox"/>	<input type="checkbox"/>
Mild (definite osteophytes)	<input type="checkbox"/>	<input type="checkbox"/>
Moderate (osteophytes, definite loss of joint space, possible sclerosis and cysts)	<input type="checkbox"/>	<input type="checkbox"/>
Severe (large osteophytes, moderate to severe loss of joint space, definite sclerosis, cysts, or subluxation)	<input type="checkbox"/>	<input type="checkbox"/>

B. Patellofemoral joint

Normal	<input type="checkbox"/>	<input type="checkbox"/>
Mild (definite osteophytes)	<input type="checkbox"/>	<input type="checkbox"/>
Moderate (osteophytes, definite loss of joint space)	<input type="checkbox"/>	<input type="checkbox"/>
Severe (large osteophytes, moderate to severe loss of joint space, subluxation)	<input type="checkbox"/>	<input type="checkbox"/>

② OTHER FINDINGS

Chondrocalcinosis	<input type="checkbox"/>	<input type="checkbox"/>
Paget's disease	<input type="checkbox"/>	<input type="checkbox"/>
Loose bodies (osteochondromatosis)	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>

Version 1.1, 9/24/98

APPENDIX 5 Excessive Bone Loss Form

Health
ABC

Health ABC Enrollment ID #	Acrosite	Date Form Completed	Staff ID #
H		Month / Day / Year	

EXCESSIVE BONE LOSS FORM**Suspected Excessive Bone Loss Checklist***(Examiner Note: Please make sure that this form is accompanied by all the items listed below.)*

- ☐ Printouts of the baseline and all follow-up scans of the hip
- ☐ Printouts of the "rate of change" report(s) you created for the hip
- ☐ Copies of baseline and all follow-up scans of the hip on floppy disk

Be sure to follow all procedures for participants with suspected excessive bone loss.

Comments: _____

_____**To be filled out by the UCSF DXA Reading Center**

- ☐ Yes, we can confirm excessive bone loss.
The scans are technically correct and the analyses are performed appropriately.
- ☐ Yes, we can confirm excessive bone loss.
However, the scans were not analyzed properly. Please reanalyze the scan(s) following our instructions and inform the participant of the correct bone loss %.
- ☐ The scans provided indicate possible excessive bone loss.
However, a second scan of the site was not performed in this participant. Excessive bone loss can only be confirmed after you have obtained a second scan of the region where bone loss is suspected. Please schedule the participant for a repeat measurement.
- ☐ After scan review we cannot confirm excessive bone loss.

Comments: _____

Signature of UCSF DXA Reading Center Reviewer _____ Date: _____

Draft

Version 1.0, 4/1/99

APPENDIX 6 Excessive Bone Loss Letter to Participant

July 13, 2002

Jane Doe
1234 Market Street
Pittsburgh, PA 15213

Dear Ms. Doe:

During your last clinic visit for the Health ABC study, we repeated measurements of your hip bone density. Analysis of the results indicated that you have lost bone in the hip at a rate greater than 3 % per year since your baseline measurement was made.

This loss is greater than average for a person your age and may indicate an increased risk of fracture. This bone loss may also be related to other health conditions, or could result from use of certain medications.

We have enclosed both copies of your hip scan, your baseline measurement and your last measurement. We suggest that you consult with your personal doctor to find out why this is occurring, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a doctor who specializes in treating osteoporosis in Pittsburgh.

Thank you for your time and interest in the Health ABC study. Please do not hesitate to call us if you have questions at (____)_____ and ask for _____.

Sincerely,

Anne Newman, M.D., M.P.H.
Health ABC Principal Investigator

/sa

APPENDIX 7 Excessive Bone Loss Letter to Physician

July 13, 2002

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

Your patient, _____, who has been a participant in the Health ABC study for the past 5 years, was here on ____/____/____ for his/her annual visit. We have measured bone mineral density of the hip with state-of-the-art densitometry machines at baseline, Year 3, and now at Year 6. The BMD scans of his/her total hip showed _____% bone loss since the start of the study. Our study experts have reviewed these scans and believe the bone loss to be real. This is considered to be a significant amount and is referred to as "excessive bone loss" by our study. Significant declines in hip BMD may indicate the presence of an important medical condition, such as vitamin D deficiency or multiple myeloma, but we cannot rule out the possibility of positioning or other measurement errors.

We are enclosing a copy of the participant's hip scan and reference plots that show the bone loss to be _____%.

If you have any questions, please feel free to contact us at (____)_____.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

/sa

APPENDIX 8 Weight Change Alert Letter for Physician

September 13, 2002

Charles Cutler, M.D.
512 Hamilton Road
Marion, PA 19066

Dear Dr. Cutler:

On September 1, 2002, _____ was seen at the Health ABC Research Clinic.

At the last clinic visit one year ago, his/her weight was _____ lbs (kgs)
The weight today was _____ lbs (kgs)

This weight is $\geq 10\%$ less than one year ago.

All tests done for Health ABC were performed for research purposes only and will be used to describe the health status of men and women in their seventies and eighties who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____.

Thanks you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Piera Kost

APPENDIX 9 Sample Letter to Physician Regarding Laboratory Alert Value

July 13, 2002

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

On July 1, 2002, we performed a surveillance visit on your patient _____ at the Health ABC Clinic. [A fasting glucose was obtained and the results of the fasting glucose are 48 mg/dL. (Alert values are <50 mg/dL or >350 mg/dL.)]

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator